23. (New) The method of claim 22, wherein the DNA is complexed with a lipid-based carrier.

24. (New) The method of claim 23, wherein the lipid-based carrier is a cationic lipid.

25. (New) The method of claim 23, wherein the lipid-based carrier is an artificial viral envelope.

26. (New) The method of claim 22, wherein the DNA is naked.

27. (New) The method of claim 21, wherein the volume of particle free air inhaled in step (b) is sufficiently large so as to approximately fill the peripheral region of the patient's lungs and wherein the volume of aerosol released in step (c) is sufficiently large so as to fill the central regions of the patient's lungs but not the upper region of anatomical dead space of the patient's respiratory tract.

28. (New) A method for generating an aerosol containing a condensed polynucleotide, comprising:

a) mixing a polynucleotide with a condensing agent in a manner effective to produce a condensed polynucleotide; and

b) forcibly applying the condensed polynucleotide to a first side of a member comprising pores having an exit diameter of 0.5-25 microns so that an aerosol is generated from the pores from a second side of the member.

29. (New) The method of claim 28, wherein the polynucleotide is a double stranded DNA expression construct.

30. (New) The method of claim 29, wherein the construct comprises a nucleotide sequence encoding a functional cystic fibrosis transmembrane conductance regulator.

31. (New) The method of claim 28, wherein the polynucleotide is a ribozyme.

32. (New) The method of claim 28, wherein the polynucleotide is an antisense oligonucleotide.

33. (New) The method of claim 32, wherein the antisense polynucleotide is complementary to elastase mRNA.

34. (New) The method of claim 28, wherein the condensing agent is protamine sulfate, polylysine, or a combination thereof.

35. (New) The method of claim 28, wherein the condensing agent is protamine sulfate.

36. (New) The method of claim 35, wherein the weight ratio of polynucleotide to protamine sulfate is from about 2:1 to about 1:11.

37. (New) The method of claim 28, wherein the polynucleotide is complexed with a lipid carrier.

38. (New) The method of claim 37, wherein the lipid carrier is selected from the group consisting of DOTMA, DOTAP and DC-Chol.

39. (New) The method of claim 28, wherein the polynucleotide is an oligonucleotide.

40. (New) The method of claim 37, wherein the lipid carrier an artificial viral envelope.

41. (New) A method for administering a condensed polynucleotide to an individual, comprising:

a) generating an aerosol comprising a condensed polynucleotide; and

b) delivering the aerosol to an individual so that the polynucleotide is deposited in the respiratory tract.

42. (New) A method for expressing a polynucleotide *in vivo*, comprising:

administering an aerosol comprising a condensed polynucleotide expression construct to an individual so that the polynucleotide is taken up and expressed by a cell in the individual.

43. (New) The method of claim 42, wherein the polynucleotide is double stranded DNA.

44. (New) A method for generating an immune response to a protein, comprising:

administering an aerosol comprising a condensed polynucleotide expression construct to the respiratory tract of an individual in a manner such that the polynucleotide is taken up and expressed by lung cells of the individual, wherein said polynucleotide comprises a nucleotide sequence that encodes an immunogenic protein that is produced in said lung cells.

45. (New) A method of transfecting lung cells *in vivo*, comprising administering an aerosol containing a condensed polynucleotide to the respiratory tract of an individual in a manner effective to transfect the lung cells.

46. (New) A method of isolating a transformed low passage lung cell line, comprising

administering an aerosol comprising a condensed polynucleotide to the lungs of an individual so that the polynucleotide is taken up by the lung cells, and isolating and culturing the transformed lung cells from the individual.

47. (New) A method of delivering recombinant viral envelope proteins comprising a condensed polynucleotide to an individual, comprising

a) passing a formulation containing said particles through pores having a size in the range of about 0.5 to about 25 microns in a manner effective to generate an aerosol; and

b) delivering the aerosol to the individual.

48. (New) A pharmaceutical composition comprising an aerosol comprising an artificial viral particle, wherein the artificial viral particle comprises an artificial viral envelope and a condensed polynucleotide, and wherein the artificial viral particle has a diameter of from about 1 to about 8 microns.

49. (New) A pharmaceutical composition comprising an aerosol comprising a condensed polynucleotide.

50. (New) A pharmaceutical composition of claim 49, wherein the particles have a diameter of from about 0.5 to about 75 microns.

51. (New) The pharmaceutical composition of claim 49, wherein the particles have a diameter from about 1 to about 8 microns.

52. (New)The pharmaceutical composition of claim 49, wherein the particles have a diameter of from about 1 to about 8 microns.

53. (New) A disposable package for use in aerosolized delivery of drugs to the lungs, comprising:

a container having at least one wall which is movable by the application of a force and having at least one opening, the container having therein a liquid, flowable formulation which includes a condensed polynucleotide;

a porous member covering the opening wherein the member pores have a diameter of about 0.5 to about 6 microns;

wherein the formulation has a viscosity sufficiently low such that the formulation is aerosolized to particles having a diameter of about 0.5 to about 12 microns when force is applied to the movable wall and moved out of the pores.

54. (New) A disposable package, comprising:

a container having an opening leading to a channel, the container having a liquid, flowable formulation therein which formulation comprises a condensed polynucleotide, wherein at least one wall of the container is movable in a manner so as to allow the formulation in the container to be forced out of the opening into the channel, and

a cavity having a surface comprising a porous member wherein pores of the member have a diameter in the range of about 0.25 to about 6 microns; and

an interconnecting component connecting the container and cavity.

55. (New) A method of drug delivery, comprising:

providing a disposable porous member having pores with a diameter in the range of about 0.25 to about 6.0 microns;

forming aerosolized particles of a formulation comprised of a carrier and a condensed polynucleotide which particles have a diameter in the range of about 0.5 to about 12.0 microns by moving the formulation through the disposable porous member;

inhaling the particles into the lungs of a patient; and

repeating the above steps as necessary, wherein a new disposable member is used each time.

56. (New) A drug delivery device, comprising:

a channel having a first opening into which air can be inhaled, a second opening from which a patient can withdraw air and a third opening through which aerosolized particles enter the channel;

a container having a formulation comprising a condensed polynucleotide therein;

a means for applying physical force to the formulation upon actuation; and

a disposable porous member through which the formulation is forced through the member having pores with a diameter of about 0.25 to about 6.0 microns.

I. REMARKS

Claims 21-56 are pending after entry of the amendments set forth herein.

Claims 1-20 were examined and were rejected in the final Office Action dated November 17, 2000.

Claims 1-20 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications. All rejections of claims 1-20 in the November 17, 2000 Office Action are rendered moot by cancellation without prejudice of claims 1-20.

New claims 21-56 are added. Support for new claims 21-56 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: page 5, lines 18-20; page 18, line 8-9; page 20, lines 8-24; page 26, line 4 to page 27, line 16; page 34, line 12; page